[3510-16-P]

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Part 1

[Docket No.: PTO-P-2013-0006]

RIN 0651-AC84

Revisions to Patent Term Adjustment

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Interim final rule.

SUMMARY: The United States Patent and Trademark Office (Office) is revising the rules of practice to implement the changes to the patent term adjustment provisions in section 1(h) of the Act to correct and improve certain provisions of the Leahy-Smith America Invents Act and title 35, United States Code (AIA Technical Corrections Act). Section 1(h) of the AIA Technical Corrections Act revises the date from which the fourteen-month patent term adjustment period is measured, and clarifies the date from which the three-year patent term adjustment period is measured, with respect to

international applications filed under the Patent Cooperation Treaty. Under section 1(h) of the AIA Technical Corrections Act, the fourteen-month patent term adjustment period and the three-year patent term adjustment period will be measured from the same date: the date on which an application was filed under 35 U.S.C. 111(a) in an application under 35 U.S.C. 111; or the date of commencement of the national stage under 35 U.S.C. 371 in an international application. Section 1(h) of the AIA Technical Corrections Act also revises the provisions for notifying applicants of patent term adjustment determinations and for requesting reconsideration and judicial review of the Office's patent term adjustment determinations and decisions.

DATES: Effective date: [Insert date of publication in the FEDERAL REGISTER].

Applicability date: The changes to 37 CFR 1.702, 1.703, and 1.705 in this interim rule apply to any patent granted on or after January 14, 2013. The change to 37 CFR 1.704 in this interim rule applies to any application in which a notice of allowance was mailed on or after [Insert date of publication in the FEDERAL REGISTER].

<u>Comment deadline date</u>: Written comments must be received on or before [Insert date 60 days after publication in the FEDERAL REGISTER].

ADDRESSES: Comments should be sent by electronic mail message over the Internet addressed to: AC84.comments@uspto.gov. Comments may also be submitted by postal mail addressed to: Mail Stop Comments--Patents, Commissioner for Patents, P.O. Box

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1450, Alexandria, VA, 22313-1450, marked to the attention of Kery A. Fries, SeniorLegal Advisor, Office of Patent Legal Administration, Office of the DeputyCommissioner for Patent Examination Policy.

Comments may also be sent by electronic mail message over the Internet via the Federal eRulemaking Portal. See the Federal eRulemaking Portal Web site (http://www.regulations.gov) for additional instructions on providing comments via the Federal eRulemaking Portal.

Although comments may be submitted by postal mail, the Office prefers to receive comments by electronic mail message over the Internet because sharing comments with the public is more easily accomplished. Electronic comments are preferred to be submitted in plain text, but also may be submitted in ADOBE® portable document format or MICROSOFT WORD® format. Comments not submitted electronically should be submitted on paper in a format that facilitates convenient digital scanning into ADOBE® portable document format.

The comments will be available for public inspection at the Office of the Commissioner for Patents, currently located in Madison East, Tenth Floor, 600 Dulany Street, Alexandria, Virginia. Comments also will be available for viewing via the Office's Internet Web site (http://www.uspto.gov). Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

FOR FURTHER INFORMATION CONTACT: Kery A. Fries, Senior Legal Advisor ((571) 272-7757), Office of Patent Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy.

SUPPLEMENTARY INFORMATION:

Executive Summary: Purpose: Section 1(h) of the AIA Technical Corrections Act revises the patent term adjustment provisions of 35 U.S.C. 154(b). The AIA Technical Corrections Act revises the date from which the fourteen-month period in 35 U.S.C. 154(b)(1)(A)(i)(II), and clarifies the date from which the three-year period in 35 U.S.C. 154(b)(1)(B), are measured with respect to international applications. Section 1(h) of the AIA Technical Corrections Act also revises the provisions in 35 U.S.C. 154(b)(3) and (b)(4) for notifying applicants of patent term adjustment determinations and for requesting reconsideration and judicial review of the Office's patent term adjustment determinations and decisions.

<u>Summary of Major Provisions</u>: The Office is revising the rules of practice pertaining to patent term adjustment for consistency with the change to 35 U.S.C. 154(b)(1)(A)(i)(II) to indicate that the fourteen-month period is measured from the date of commencement of the national stage under 35 U.S.C. 371 in an international application. The change to 35 U.S.C. 154(b)(1)(B) does not require a change to the rules of practice, as the current rules of practice interpret the phrase "actual filing date of the application in the United

States" in former 35 U.S.C. 154(b)(1)(B) as meaning the date of commencement of the national stage under 35 U.S.C. 371 in an international application.

The Office is also revising the provisions pertaining to seeking reconsideration of a patent term adjustment determination, in light of the changes to 35 U.S.C. 154(b)(3) and (b)(4). The Office is continuing to provide that any request for reconsideration of the patent term adjustment indicated on the patent must be filed within two months from the date the patent was granted. The Office is revising this provision to indicate that this two-month time period may be extended by an additional five months, permitting an applicant to request reconsideration of the patent term adjustment indicated on the patent as late as seven months after the date the patent was granted.

<u>Costs and Benefits</u>: This rulemaking is not economically significant under Executive Order 12866 (Sept. 30, 1993).

Background: The AIA Technical Corrections Act was enacted on January 14, 2013.

See Pub. L. 112-274, 126 Stat. 2456 (2013). Section 1(h) of the AIA Technical

Corrections Act revises the patent term adjustment provisions of 35 U.S.C. 154(b). See 126 Stat. at 2457.

Section 1(h)(1)(A) of the AIA Technical Corrections Act amends 35 U.S.C. 154(b)(1)(A)(i)(II) to change "the date on which an international application fulfilled the requirements of section 371" to "the date of commencement of the national stage under

section 371 in an international application." See id. Under former 35 U.S.C. 154(b)(1)(A)(i)(II), the fourteen-month period in 35 U.S.C. 154(b)(1)(A)(i) was measured from "the date on which an international application fulfilled the requirements of section 371 of this title," and an international application does not fulfill the requirements of 35 U.S.C. 371 until the applicant files (inter alia) the inventor's oath or declaration (35 U.S.C. 371(c)(4) and MPEP § 1893.03(b)). See Changes to Implement the Inventor's Oath or Declaration Provisions of the Leahy-Smith America Invents Act, 77 FR 48776, 48780 (Aug. 14, 2012). Thus, under section 1(h)(1)(A) of the AIA Technical Corrections Act, the fourteen-month period in 35 U.S.C. 154(b)(1)(A)(i) is measured from: (1) the date on which an application was filed under 35 U.S.C. 111(a); or (2) the date of commencement of the national stage under 35 U.S.C. 371 in an international application.

Section 1(h)(1)(B) of the AIA Technical Corrections Act amends 35 U.S.C. 154(b)(1)(B) to change "the actual filing date of the application in the United States" to "the actual filing date of the application under section 111(a) in the United States or, in the case of an international application, the date of commencement of the national stage under section 371 in the international application." See 126 Stat. at 2457. Thus, under section 1(h)(1)(B) of the AIA Technical Corrections Act, the three-year period in 35 U.S.C. 154(b)(1)(B) is measured from: (1) the actual filing date of the application under 35 U.S.C. 111(a) in the United States; or (2) in the case of an international application, the date of commencement of the national stage under 35 U.S.C. 371 in the international application.

The change to 35 U.S.C. 154(b)(1)(A)(i)(II) requires a change in Office practice, as the date of commencement of the national stage under 35 U.S.C. 371 is not always the date on which an international application fulfilled the requirements of 35 U.S.C. 371. However, the change to 35 U.S.C. 154(b)(1)(B) does not require a change in Office practice, because, since the patent term adjustment provisions of 35 U.S.C. 154(b) were implemented in September of 2000, the Office has interpreted the phrase "actual filing" date of the application in the United States" in former 35 U.S.C. 154(b)(1)(B) as the date of commencement of the national stage under 35 U.S.C. 371 in an international application. See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 FR 56365, 56382-84 (Sept. 18, 2000) (explaining why the phrase "actual filing date of the application in the United States" in 35 U.S.C. 154(b)(1)(B) must mean the date the national stage commenced under 35 U.S.C. 371(b) or (f) in the case of an international application). The change to 35 U.S.C. 154(b)(1)(A)(i)(II) and (b)(1)(B) in section 1(h)(1) of the AIA Technical Corrections Act means that the fourteen-month period in 35 U.S.C. 154(b)(1)(A)(i) and the three-year period in 35 U.S.C. 154(b)(1)(B) will be measured from the same date: (1) the date on which an application was filed under 35 U.S.C. 111(a) in an application under 35 U.S.C. 111; or (2) the date of commencement of the national stage under 35 U.S.C. 371 in an international application.

Section 1(h)(2) of the AIA Technical Corrections Act amends 35 U.S.C. 154(b)(3)(B)(i) to change "shall transmit a notice of that [patent term adjustment] determination with the

written notice of allowance of the application under section 151" to "shall transmit a notice of that [patent term adjustment] determination no later than the date of issuance of the patent." See 126 Stat. at 2457. This change eliminates the need for the Office to provide an initial patent term adjustment determination with the notice of allowance and before the patent term adjustment under 35 U.S.C. 154(b)(1)(A)(iv) and 154(b)(1)(B) is known. See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 FR 56365, 56374 (explaining that a two-part process is required because the Office is obliged under 35 U.S.C. 154(b)(3) to provide a patent term adjustment determination before the issue date, and thus the patent term adjustment, is known).

Section 1(h)(3) of the AIA Technical Corrections Act amends 35 U.S.C. 154(b)(4) to change "[a]n applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the grant of the patent" to "[a]n applicant dissatisfied with the Director's decision on the applicant's request for reconsideration under paragraph (3)(B)(ii) shall have exclusive remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the date of the Director's decision on the applicant's request for reconsideration." See 126 Stat. at 2457. This change to 35 U.S.C. 154(b)(4) clarifies that: (1) a civil action under 35 U.S.C. 154(b)(4) is not an alternative to requesting reconsideration of a patent term adjustment under 35 U.S.C. 154(b)(3), but is the remedy for an applicant who is dissatisfied with the Director's decision on the applicant's request for reconsideration; and (2) a civil action under 35 U.S.C. 154(b)(4) is

the exclusive remedy for an applicant who is dissatisfied with the Director's decision on the applicant's request for reconsideration.

Section 1(n) of the AIA Technical Corrections Act provides that amendments made by the AIA Technical Corrections Act shall take effect on January 14, 2013 (the date of enactment of the AIA Technical Corrections Act), and shall apply to proceedings commenced on or after January 14, 2013. See 126 Stat. at 2459. Section 1(n) of the AIA Technical Corrections Act does not limit the applicability of the changes in section 1(h) to applications filed on or after January 14, 2013. Cf. Section 4405(a) of the American Inventors Protection Act of 1999 (AIPA), Pub. L. 106-113, 113 Stat. 1501, 1501A-552 through 1501A-591 (1999) (limiting the applicability of the patent term adjustment provisions of the AIPA to applications filed on or after May 29, 2000 (the date that is six months after the date of the enactment of AIPA). Patent term adjustment proceedings are not "commenced" until the Office notifies the applicant of the Office's patent term adjustment under 35 U.S.C. 154(b)(3), which now occurs when the patent is granted. Therefore, the changes to 35 U.S.C. 154 in section 1(h) of section 1(n) of the AIA Technical Corrections Act apply to any patent granted on or after January 14, 2013.

Discussion of Specific Rules

The following is a discussion of the amendments to Title 37 of the Code of Federal Regulations, Part 1.

Section 1.702: Section 1.702(a)(1) is amended to measure the fourteen-month period from the date of commencement of the national stage 35 U.S.C. 371(b) or (f) in an international application. Section 1.702(a)(1)(i) now specifically states that a ground for potential patent term adjustment is the failure of the Office to: "Mail at least one of a notification under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151 not later than fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) or the date the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application."

Section 1.702(b) is amended to change the paragraph heading to "<u>Three-year pendency</u>." No further change to 1.702(b) is necessary, as the Office has interpreted the phrase "actual filing date of the application in the United States" in former 35 U.S.C. 154(b)(1)(B) as the date of commencement of the national stage under 35 U.S.C. 371 in an international application since the patent term adjustment provisions of 35 U.S.C. 154(b) were implemented in September of 2000 (as discussed previously).

Section 1.703: Section 1.703(a)(1) is amended to measure its fourteen-month period from the date of commencement of the national stage 35 U.S.C. 371(b) or (f) in an international application. Section 1.703(a)(1)(i) now specifically states that the applicable time period is: "The number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) or the date the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date of mailing of either an action

under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first."

No change to § 1.703(b) is necessary, as the Office has interpreted the phrase "actual filing date of the application in the United States" in former 35 U.S.C. 154(b)(1)(B) as the date of commencement of the national stage under 35 U.S.C. 371 in an international application since the patent term adjustment provisions of 35 U.S.C. 154(b) were implemented in September of 2000 (as discussed previously).

Section 1.704: Section 1.704(c) is amended to remove the reference to an application for patent term adjustment under § 1.705. Section 1.705 no longer provides for a request for reconsideration of the patent term adjustment indicated in the notice of allowance, as 35 U.S.C. 154(b)(3) no longer requires a patent term adjustment with the notice of allowance.

35 U.S.C. 154(b)(3)(C) (implemented in § 1.705(c)) provides for reinstatement of all or part of the period of adjustment reduced pursuant to 35 U.S.C. 154(b)(2)(C) if the applicant makes a showing that, in spite of all due care, the applicant was unable to respond within the three-month period, but requires that such a showing be made "prior to the issuance of the patent." Thus, § 1.704(e) continues to provide that the submission of a request under § 1.705(c) for reinstatement of reduced patent term adjustment will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under § 1.704(c)(10).

Section 1.705: Section 1.705(a) provides that the patent will include notification of any patent term adjustment under 35 U.S.C. 154(b). This change is due to the change to 35 U.S.C. 154(b)(3) to no longer require notice of a patent term adjustment with the notice of allowance. The Office plans to continue to provide an indication of the patent term adjustment with the issue notification, but the patent term adjustment under 35 U.S.C. 154(b) indicated on the patent is the "official" notification of the Office's patent term adjustment determination.

Section 1.705(b) provides that any request for reconsideration of the patent term adjustment indicated on the patent must be by way of an application for patent term adjustment filed no later than two months from the date the patent was granted, and that this two-month time period may be extended under the provisions of § 1.136(a) by five months. This provision permits an applicant to request reconsideration of the patent term adjustment indicated on the patent as late as seven months after the date the patent was granted. Section 1.705(b) no longer provides for a request for reconsideration of the Office's patent term adjustment determination prior to the grant of a patent.

The Office has adopted <u>ad hoc</u> procedures for seeking reconsideration of the patent term adjustment determination when there have been changes (<u>sua sponte</u> or as a result of court decisions) to the Office's interpretation of the provisions of 35 U.S.C. 154(b). <u>See Revision of Patent Term Adjustment Provisions Relating to Appellate Review</u>, 77 FR 49354, 49356 (Aug. 16, 2012), and Interim Procedure for Patentees To Request a

Recalculation of the Patent Term Adjustment To Comply With the Federal Circuit

Decision in Wyeth v. Kappos Regarding the Overlapping Delay Provision of 35 U.S.C.

154(b)(2)(A), 75 FR 5043, 5044 (Feb. 1, 2010). These ad hoc procedures were adopted because former 35 U.S.C. 154(b)(4) provided a time period for seeking judicial review that was not related to the filing of a request for reconsideration of the Office's patent term adjustment determination or the date of the Office's decision on any request for reconsideration of the Office's patent term adjustment determination. In view of the changes to 35 U.S.C. 154(b)(3) and 154(b)(4), and to permit patentees additional time to determine whether to request reconsideration of the Office's patent term adjustment determination, the Office is providing in § 1.705(b) that its two-month time period may be extended under the provisions of § 1.136(a) (permitting an applicant to request reconsideration of the patent term adjustment indicated on the patent as late as seven months after the date the patent was granted).

Section 1.705(c) is amended to provide that any request for reinstatement of all or part of the period of adjustment reduced pursuant to § 1.704(b) for failing to reply to a rejection, objection, argument, or other request within three months of the date of mailing of the Office communication notifying the applicant of the rejection, objection, argument, or other request must be filed prior to the issuance of the patent, and that this time period is not extendable. 35 U.S.C. 154(b)(3)(C) requires that such a showing be made "prior to the issuance of the patent," and thus the Office cannot permit the showing provided for in 35 U.S.C. 154(b)(3)(C) and § 1.705(c) to be submitted with a request for reconsideration of the Office's patent term adjustment determination under § 1.705(b).

The former provisions of §§ 1.705(d) and (e) have been removed in view of the changes to 1.705(b).

Rulemaking Considerations:

A. Administrative Procedure Act: This rulemaking revises the rules of practice in patent cases to implement the changes to the patent term adjustment provisions of 35 U.S.C. 154(b) in the AIA Technical Corrections Act. The revisions pertaining to 35 U.S.C. 154(b)(1) simply revise the provisions of 37 CFR 1.702 and 1.703 for consistency with the changes to 35 U.S.C. 154(b)(1). The revisions pertaining to 35 U.S.C. 154(b)(3) simply revise 37 CFR 1.704 and 1.705 to change (extend) the time period for seeking reconsideration of a patent term adjustment determination in light of the changes to 35 U.S.C. 154(b)(3). These changes do not alter the substantive criteria of patentability or patent term adjustment. Therefore, these changes involve rules of agency practice and procedure and/or interpretive rules. See Bachow Commc'ns Inc. v. FCC, 237 F.3d 683, 690 (D.C. Cir. 2001) (rules governing an application process are procedural under the Administrative Procedure Act); Inova Alexandria Hosp. v. Shalala, 244 F.3d 342, 350 (4th Cir. 2001) (rules for handling appeals were procedural where they did not change the substantive standard for reviewing claims); National Whistleblower Ctr. v. Nuclear Regulatory Comm'n, 208 F.3d 256, 262 (D.C. Cir. 2000) (rules that prescribe a timetable for asserting rights are procedural, unless they foreclose an effective opportunity to make one's case on the merits) (quoting Lamoille Valley R.R. Co. v. ICC,

711 F.2d 295, 328 (D.C. Cir. 1983)); and Nat'l Org. of Veterans' Advocates v. Sec'y of Veterans Affairs, 260 F.3d 1365, 1375 (Fed. Cir. 2001) (rule that clarifies interpretation of a statute is interpretive). In addition, good cause exists to make these procedural changes without prior notice and opportunity for comment and to be effective immediately so as to avoid inconsistency between the provisions of 37 CFR 1.702 through 1.705 and 35 U.S.C. 154(b) as amended by the AIA Technical Corrections Act.

Accordingly, prior notice and opportunity for public comment are not required pursuant to 5 U.S.C. 553(b) or (c) (or any other law) and thirty-day advance publication is not required pursuant to 5 U.S.C. 553(d) (or any other law). See Cooper Techs. Co. v. Dudas, 536 F.3d 1330, 1336-37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), does not require notice and comment rulemaking for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice") (quoting 5 U.S.C. 553(b)(A)). The Office, however, is publishing these changes as an interim rule to allow for public comments because the Office seeks the benefit of the public's views on the Office's implementation of the changes to 35 U.S.C. 154(b) in the AIA Technical Corrections Act.

B. Regulatory Flexibility Act: For the reasons set forth herein, the Deputy General Counsel for General Law of the United States Patent and Trademark Office has certified to the Chief Counsel for Advocacy of the Small Business Administration that changes in this rulemaking will not have a significant economic impact on a substantial number of small entities. See 5 U.S.C. 605(b).

The changes in this rulemaking: (1) revise the date from which the fourteen-month period in 35 U.S.C. 154(b)(1)(A)(i) is measured in an international application for consistency with the change to 35 U.S.C. 154(b)(1)(A)(i)(II); and (2) revise (extend) the time period for seeking reconsideration of the Office's patent term adjustment in view of the changes in 35 U.S.C. 154(b)(3) and (b)(4). These changes mirror the provisions in the AIA Technical Corrections Act and do not add any additional requirements (including information collection requirements) or fees for patent applicants or patentees. For these reasons, the changes in this rulemaking will not have a significant economic impact on a substantial number of small entities.

- C. Executive Order 12866 (Regulatory Planning and Review): This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).
- D. Executive Order 13563 (Improving Regulation and Regulatory Review): The Office has complied with Executive Order 13563. Specifically, the Office has, to the extent feasible and applicable: (1) made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private

sector and the public as a whole, and provided on-line access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

- **E. Executive Order 13132 (Federalism):** This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).
- **F. Executive Order 13175 (Tribal Consultation):** This rulemaking will not: (1) have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).
- G. Executive Order 13211 (Energy Effects): This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

- **H.** Executive Order 12988 (Civil Justice Reform): This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).
- **I. Executive Order 13045 (Protection of Children):** This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).
- **J. Executive Order 12630 (Taking of Private Property):** This rulemaking will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).
- K. Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), the United States Patent and Trademark Office will submit a report containing this interim rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this rulemaking will not result in an annual effect on the economy of 100 million dollars or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this rulemaking is not a "major rule" as defined in 5 U.S.C. 804(2).

- L. Unfunded Mandates Reform Act of 1995: The changes set forth in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of 100 million dollars (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of 100 million dollars (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. See 2 U.S.C. 1501 et seq.
- **M.** National Environmental Policy Act: This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. See 42 U.S.C. 4321 et seq.
- N. National Technology Transfer and Advancement Act: The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions which involve the use of technical standards.
- O. Paperwork Reduction Act: The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) requires that the Office consider the impact of paperwork and other information collection burdens imposed on the public. The rules of practice pertaining to patent term adjustment and extension have been reviewed and approved by the Office of

Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) under OMB control number 0651-0020. The changes in this rulemaking: (1) revise the date from which the fourteen-month period in 35 U.S.C. 154(b)(1)(A)(i) is measured in an international application for consistency with the change to 35 U.S.C. 154(b)(1)(A)(i)(II); and (2) revise (extend) the time period for seeking reconsideration of the Office's patent term adjustment in view of the changes in 35 U.S.C. 154(b)(3) and (b)(4). This rulemaking does not add any additional requirements (including information collection requirements) or fees for patent applicants or patentees. Therefore, the Office is not resubmitting information collection packages to OMB for its review and approval because the changes in this rulemaking do not affect the information collection requirements associated with the information collections approved under OMB control number 0651-0020 or any other information collections.

Notwithstanding any other provision of law, no person is required to respond to nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Courts, Freedom of Information, Inventions and patents, Reporting and record keeping requirements, Small Businesses.

For the reasons set forth in the preamble, 37 CFR part 1 is amended as follows:

PART 1 - RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR Part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2).

2. Section 1.702 is amended by revising paragraph (a)(1) and the heading of paragraph (b) to read as follows:

§ 1.702 Grounds for adjustment of patent term due to examination delay under the Patent Term Guarantee Act of 1999 (original applications, other than designs, filed on or after May 29, 2000).

- (a) * * *
- (1) Mail at least one of a notification under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151 not later than fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) or the date the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application;

* * * * *

(b) Three-year pendency. * * *

* * * * *

3. Section 1.703 is amended by revising paragraph (a)(1) to read as follows:

§ 1.703 Period of adjustment of patent term due to examination delay.

- (a) * * *
- (1) The number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) or the date the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first;
- 4. Section 1.704 is amended by revising paragraph (e) to read as follows:

§ 1.704 Reduction of period of adjustment of patent term.

* * * * *

- (e) The submission of a request under § 1.705(c) for reinstatement of reduced patent term adjustment will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraph (c)(10) of this section.
- 5. Section 1.705 is amended by removing paragraphs (d) and (e), redesignating paragraph (f) as paragraph (d), and revising paragraph (a), the introductory text of paragraph (b), and the introductory text of paragraph (c) to read as follows:

§ 1.705 Patent term adjustment determination.

(a) The patent will include notification of any patent term adjustment under 35

U.S.C. 154(b).

(b) Any request for reconsideration of the patent term adjustment indicated on the

patent must be by way of an application for patent term adjustment filed no later than two

months from the date the patent was granted. This two-month time period may be

extended under the provisions of § 1.136(a). An application for patent term adjustment

under this section must be accompanied by:

* * * * *

(c) Any request for reinstatement of all or part of the period of adjustment reduced

pursuant to § 1.704(b) for failing to reply to a rejection, objection, argument, or other

request within three months of the date of mailing of the Office communication notifying

the applicant of the rejection, objection, argument, or other request must be filed prior to

the issuance of the patent. This time period is not extendable. Any request for

reinstatement of all or part of the period of adjustment reduced pursuant to § 1.704(b)

under this paragraph must also be accompanied by:

* * * * *

Date: March 25, 2013

Teresa Stanek Rea

Acting Under Secretary of Commerce for Intellectual Property and

Acting Director of the United States Patent and Trademark Office

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